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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,179	08/08/2001	Paula M. Jardieu	P0718P2C1D1C1	5112

9157 7590 06/07/2004  
GENENTECH, INC.  
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SOUTH SAN FRANCISCO, CA 94080

EXAMINER

BLANCHARD, DAVID J

ART UNIT PAPER NUMBER

1642

DATE MAILED: 06/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/925,179

Applicant(s)

JARDIEU ET AL.

Examiner

David J Blanchard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 58-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 58-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. The amendments to the claims filed 12/22/2003 removing the "s" from the term "residues" is not readily apparent. To clarify the record, a clean copy of the claims, which incorporates all of the amendments filed 12/22/2003 as well as any amendments in response to this Office Action is kindly requested.
2. Claims 58-78 are pending and under examination.

### ***Specification***

3. The substitute specification filed 4/26/2004 is in compliance with 37 CFR 1.125(b) and has been entered in full. According to Applicant's statements, the substitute specification incorporates all of the amendments to the specification, corrects all defects and is free of new matter.

### **Double Patenting**

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 58-78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No.

6,329,509 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are drawn to a humanized anti-IgE antibody comprising the variable heavy chain and the variable light chain sequence of MAE11v1 (SEQ ID NOS:8 and 9, respectively), wherein at least one light chain Kabat residues 13, 19, 58, 78 or 104 has been substituted or at least one heavy chain Kabat residues 48, 49, 60, 61, 63, 67, 69, 82 or 82c has been substituted, wherein Kabat residue 60 is substituted with an amino acid residue selected from the group consisting of asparagine, glutamine, histidine, lysine or arginine; Kabat residue 61 is substituted with an amino acid residue selected from the group consisting of proline, glycine, alanine, valine, leucine or isoleucine, and the humanized anti-IgE antibody is an IgG1, IgG2, IgG3 or an IgG4. In claim 58, the phrase "at least" is interpreted as open language meaning that any one Kabat VH or VL residue is substituted as well as up to all of the recited VH residues are substituted and up to all of the recited VL residues are substituted and all of the recited VH and VL residues are substituted.

Claims 1-20 of U.S. Patent No. 6,329,509 B1 are drawn to a humanized antibody comprising a VH domain comprising SEQ ID NO:8 and a VL domain comprising SEQ ID

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NO:9, which share 100% identity with SEQ ID NOS:8 and 9 in the instant application (see the alignment attached to the back of this Office Action). The humanized antibody comprises an asparagine residue substituted at Kabat residue 60 (see claims 1, 6, 11 and 16) and a proline residue substituted at Kabat residue 61 (see claims 1, 6 and 11) and the humanized antibody is an IgG1, IgG2, IgG3, or an IgG4 (see claims 2-5, 7-10, 12-15 and 17-20).

### **Conclusion**

6. No claim is allowed.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (571) 272-0841. The official fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

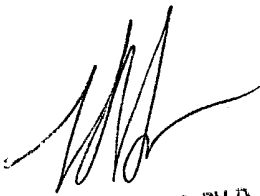
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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,  
David J. Blanchard  
571-272-0827



LARRY R. HELMS, PH.D  
PRIMARY EXAMINER